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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,242	07/31/2000	Benjamin D. Pless	473912000100	3876

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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 05/12/2003 *14*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/629,242

Applicant(s)

PLESS, BENJAMIN D.

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 14 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-22 and 24-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

Applicant's arguments filed February 14, 2003 have been fully considered but they are not persuasive. All light sources produce a predetermined pattern of light. When this pattern radiates on tissue containing a photosensitizer, the areas exposed to the light pattern are affected, in this case producing a lesion. The pattern of the lesions is directly related to, and unalterable from the pattern of the light.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 cites a "heat-free" treatment method using PDT with a photosensitizer. It is not clear how the reaction to create the singlet oxygen could occur in a heat-free manner.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent 6,143,019 to Motamedi et al. Motamedi et al teaches a method for cardiac tissue

ablation (lesion) using light activated substances with photodynamic therapy (Col. 6, lines 3-7)

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for modification of tissues responsible for cardiac arrhythmias (abstract). All light sources, including a single source, produce light in a predetermined pattern that will produce a predetermined result on sensitized tissue. Although no heat is actively used in the treatment, it cannot be a heat-free treatment due to the heat involved in creating the singlet oxygen. A ectopic focus associated with a ventricle tachycardia is disclosed a specific type of arrhythmia implying the treatment of that condition.

Claims 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,974 to Oron et al. Oron discloses a catheter for biostimulation of cardiac tissue using electromagnetic radiation that may be visible light (abstract). The light emitting area is disclosed as being flexible with the radiating element in a cutaway section (window) and a lens for emitting the beam in an outward radial direction (Col. 22, lines 42-52). The radiating area is surrounded by the catheter body (opaque) and is linear for a length of 2-3 cm (Col. 22, line 56). The opaqueness of the catheter is implied by operation in contact with the tissue minimizes absorption by blood in the heart (Col. 23, lines 2-4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,143,019 to Motamedi et al. Motamedi et al is discussed above. It is inherent that the light activated substances must be introduced into the tissue in some manner. Whether the photosensitizer is introduced locally or systemically would have been obvious to the skilled artisan.

Claims 5-10 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,143,019 to Motamedi et al as applied to claims 1 and 11 and further in view of U.S. Patent 6,164,283 to Lesh. Motamedi et al is discussed above for treating cardiac arrhythmias, but fails to disclose specific treatment areas. Lesh teaches methods to electrically isolate specific areas of the heart using ablative means to treat arrhythmia. Both interrupt the cardiac electrical process by ablating (creating lesions). This establishes the PDT technique as an alternative equivalent to RF ablation for interrupting this activity. Lesh teaches that focal arrhythmia often originate from a tissue region along the pulmonary veins of the left atrium, and even more particularly in the superior pulmonary veins. The method of treating involves forming a circumferential conduction block, using an internal catheter with ablation means, which is located either (a) along a circumferential path of tissue in a pulmonary vein wall which circumscribes the pulmonary vein lumen and transects the electrical conductivity of the pulmonary vein relative to its longitudinal axis, or (b) along a circumferential path of tissue in a left posterior atrial wall which surrounds a pulmonary vein ostium and electrically isolates the pulmonary vein and the ostium from a substantial portion of the left posterior atrial wall including the other of the vein ostia. Lesh further teaches an external procedure wherein a circumferential conduction block of one or more pulmonary veins may be performed in an epicardial ablation procedure, wherein an ablation element is either placed around the target pulmonary vein or is translated circumferentially around it while being energized to ablate the adjacent tissue in an "outside-in" approach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodynamic techniques of Motamedi et al as an alternative equivalent to the RF ablative methods for treating cardiac arrhythmias in the patterns and areas as taught by Lesh.

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Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,974 to Oron et al. Oron is discussed above but does not disclose LED's as a light source. The use of LED's is well known in the art and therefore it would have been obvious to use LED's in the device of Oron as a viable light source.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M Johnson, III  
Patent Examiner  
Art Unit 3739

Hmj  
May 5, 2003



Lee Cohen  
Primary Examiner